

FINDING OF NO SIGNIFICANT IMPACT

for

Dectomax Pour-On Solution for Cattle

NADA 141-095

Pfizer, Inc.
New York, NY

For Public Display
(HFA-305)

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for

DECTOMAX[®] Pour-On Solution for Cattle

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New York, NY**

The Center for Veterinary Medicine has considered the potential environmental impact of this action and has concluded that this action will not have a significant impact on the quality of the human environment and, therefore, an environmental impact statement will not be prepared.

Pfizer Inc. has submitted a supplement to new animal drug application (NADA) 140-095: DECTOMAX[®] pour-on antiparasitic solution for the treatment and control of internal and external parasites in cattle. The product is to be applied at 0.5mg doramectin/kg body weight topically along the mid-line of the back using an appropriate dosing device. The supplement to the NADA was submitted to change persistent efficacy periods for certain parasites. CVM denied Pfizer's request for a categorical exclusion from the requirement to prepare an environmental assessment (EA) for this supplement based on information that increased the Center's concern for the safety of avermectins in the environment. In support of the application, the drug sponsor has submitted an updated EA, dated June 2002.

The EA provides environmental fate and effects data from the original doramectin pour-on EA (August, 1996); and updated literature reviews, pattern of use information and estimates of no-observed-effect concentrations for selected invertebrates. Evaluations of potential effects on beetle populations, dung degradation processes, and higher trophic levels are provided. The updated EA addresses Agency concerns about the potential effects of doramectin residues on insect populations in dung, higher trophic levels, and chronic effects on soil organisms.

As discussed in the EA, doramectin and other avermectins are recognized to be highly toxic to a variety of insects that use cattle dung for growth and reproduction. In order to allow users to make informed decisions about the use of such products, the following statement is to be included on package inserts for avermectin-based cattle products:

As with other avermectins, doramectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

We have reviewed the EA and find that it is adequate to determine that significant environmental impacts are not expected from the approval of this supplemental NADA.

April 1, 2003
Date

Steven D. Vaughan
Director, Office of New Animal Drug Evaluation, HFV-100

Attachment: June 2002, Environmental Assessment